PROPOSED REGULATORY LANGUAGE

[Home Respiratory Care]

Amend section 1399.302 of Article 1 of Division 13.6 of Title 16 of the California Code of Regulations as follows:

§ 1399.302. Definitions

Unless the context otherwise requires, the following definitions shall apply:

- (a) "Board" means the Respiratory Care Board of California.
- (b) "B&PC" means the Business and Professions Code.
- (c) "Act" means the Respiratory Care Practice Act.
- (d) "Direct Supervision" means assigned to a currently licensed respiratory care practitioner who is on duty and immediately available in the assigned patient area.
- (e) "Employer" means any company, corporation, partnership, health maintenance organization, or any other entity or person that employs <u>or contracts with</u>, one or more respiratory care practitioners <u>or unlicensed personnel to provide respiratory care services as provided in the Act</u>.
- (f) "Licensed Home Care Employer" means a Home Medical Device Retail Facility, Home Health Agency, or any home care provider licensed by the Department of Health Services or its successor.
- (f g) "Regulations" means Division 13.6 of Title 16 of the California Code of Regulations.
- (h) "Unlicensed Personnel" means an individual not otherwise authorized or exempt to provide respiratory care services except as provided for in this article.

NOTE: Authority cited: Sections 3704 and 3722, Business and Professions Code. Reference: Sections 3704 and 3722, Business and Professions Code.

Adopt section 1399.360 of Article 6 of Division 13.6 of Title 16 of the California Code of Regulations as follows:

Title 6. Scope of Practice

§1399.360. Unlicensed Personnel Services; Home Care

- (a) Unlicensed personnel (UP) may perform limited and basic respiratory care or respiratory care related services identified in subdivisions (b), and (c), in the home setting or for the purposes of patient transfer to the home setting, provided the following conditions are met:
- (1) The UP is providing services through his or her employment with a Licensed Home Care Employer (LHCE);

- (2) The UP has been provided initial training, ongoing in-service education, and periodic competency testing specific to each service and equipment-type by either a California licensed respiratory care practitioner (RCP) or other qualified licensed personnel, in accordance with his or her scope of practice, and documentation of such training, education and testing is maintained by the LHCE for a period of four years, and
- (3) The LHCE ensures that the patient, the patient's family, or the patient's caregiver(s) are advised prior to or at the time equipment or supplies are delivered, that a RCP or other qualified licensed personnel, in accordance with his or her scope of practice, shall provide follow up checks, by telephone or in-person as appropriate, at the request of the patient or the patient's family, caregiver, or physician, or any person who has had contact with the patient, or as otherwise directed by a plan of care, and such services are provided accordingly.

(b) In accordance with this section and as it relates to:

- positive airway pressure (with or without a back-up rate) devices and supplies;
- intermittent positive pressure breathing devices and supplies;
- ventilatory devices and supplies;
- nasotracheal or tracheal suctioning devices and supplies;
- apnea monitors and alarms and supplies;
- tracheostomy care devices and supplies;
- respiratory diagnostic testing devices and supplies, including but not limited to pulse oximetry, CO2 monitoring, and spirometry devices and supplies;
- pulse-dose type or demand conserving oxygen delivery devices or high flow oxygen systems beyond the capabilities of a simple mask or cannula or requiring particulate or molecular therapy in conjunction with oxygen, and
- any other respiratory care equipment and supplies not identified in subdivisions (b) and (c),

(1) UP may:

- (A) Deliver equipment and supplies;
- (B) Instruct the patient, the patient's family or the patient's caregiver(s) on how to order equipment and supplies and the telephone number to call 24 hours a day, 7 days a week, in case of emergency in which a live person will be available to respond;
- (C) Set up equipment to the extent that the set-up is not dependent upon or influenced by any written or oral communication with the patient or the patient's family, caregiver(s) or physician (with the exception of identifying a physical location in the home for set-up), and
- (D) Provide instruction to the patient, the patient's family or the patient's caregiver(s) limited to the mechanical operation of the equipment (e.g. switch, knob, and dial locations) or the general use of equipment or supplies.

(2) UP are prohibited from:

- (A) Setting up equipment to an extent that it constitutes patient care such as applying any device to the patient or making any adjustment or taking any action that requires or is dependent upon or influenced by any written or oral communication with the patient or the patient's family, caregiver(s) or physician;
- (B) Providing any instruction to an extent that it constitutes patient care such as, instruction in the operation or use of the equipment for the purpose of deriving an intended medical benefit, or instruction in the clinical application of equipment and/or supplies;
 - (C) Performing any level of clinical assessment of the patient;
- (D) Directly engaging in any discussion of clinical care plans, therapy, prescriptions, or clinical application;
- (E) Touching the patient for the purposes of making an assessment or placing any device upon the patient, and
 - (F) Providing any service that is not expressly authorized by this section.
- (c) In accordance with this section and as it relates to oxygen delivery systems and prefilled cylinders, with the exception of pulse-dose or demand conserving oxygen systems and high flow oxygen systems beyond the capabilities of a simple mask or cannula or requiring particulate or molecular therapy in conjunction with oxygen,

(1) <u>UP may:</u>

- (A) Deliver equipment and supplies;
- (B) Instruct the patient, the patient's family or the patient's caregiver(s) on how to order oxygen equipment and supplies and the telephone number to call 24 hours a day, 7 days a week, in case of emergency in which a live person will be available to respond;
- (C) Instruct the patient, the patient's family or the patient's caregiver(s) in the proper and safe operation of oxygen equipment including:
 - (i) equipment set-up for the purpose of making the equipment patient-ready;
 - (ii) connecting disposable tubing, cannulas, and masks;
 - (iii) verification of oxygen flow;
 - (iv) demonstration to the patient of prescribed flow rate(s);
 - (v) connection and cleaning of oxygen humidifying equipment and devices;
 - (vi) use of portable back-up oxygen cylinders and equipment, and
 - (vii) removal and disposition of disposable tubing, cannulas, and masks, and
 - (D) Use a mock, self-demonstration as a method of instruction for subdivision (c)(1)(C).
- (E) Conduct regular in-home evaluations and gather information from the patient and home setting pertaining to the set-up, instruction, and provision of information as described in this subdivision for the use of the prescribing physician.

(2) UP are prohibited from:

- (A) Direct administration of home oxygen;
- (B) Handling or adjusting home oxygen equipment while it is in use by the patient or on the patient;
- (C) Touching the patient or placing any device upon the patient while engaged in the set-up and instruction of equipment, including, but not limited to, applying a cannula or performing an oximetry evaluation or oxygen saturation test, and
- (D) <u>Directly engaging in any discussion of clinical care plans, oxygen therapy or any</u> modifications of physician prescribe equipment, dosages, or instructions or clinical applications.

Authority: Business and Professions Code, Section 3722 and 3765. Reference: Business and Professions Code Sections 3701, 3702, 3703, 3704, 3705, 3706, 3717, 3731, 3760, 3761, 3762, 3763, 3764, 3765, 3766, 3767, 3768, and 3778 and Health and Safety Code Sections 1725, 1726, 1727.1, 109948, 109948.1, 111656, and 111656.3.